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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/277,401 03/26/99 JAYE M 22944-USA

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EXAMINER

TUNG, P

ART UNIT

PAPER NUMBER

1652

4

DATE MAILED:

10/02/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

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Office Action Summary

Application No.
09/277,401

Applicant(s)
Jaye et al.

Examiner
Peter Tung

Group Art Unit
1652



☐ Responsive to communication(s) filed on _____

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 1 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-65 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☐ Claim(s) _____ is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims 1-65 are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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DETAILED ACTION

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-6, drawn to LIPG antisense DNA, classified in class 536, subclass 24.5.
 - II. Claim 7, drawn to anti-LIPG antibody, classified in class 530, subclass 387.1.
 - III. Claim 8 and 9, drawn to DNA encoding anti-LIPG antibody, classified in class 536, subclass 23.5.
 - IV. Claim 10, drawn to intracellular binding protein, classified in class 530, subclass 350.
 - V. Claim 11 and 12, drawn to DNA encoding intracellular binding protein, classified in class 536, subclass 23.5.
 - VI. Claim 13, drawn to LIPG enzymatic activity inhibitor, classified in class 435, subclass 198.
 - VII. Claims 14-18, drawn to a ribozyme LIPG expression inhibitor, classified in class 536, subclass 24.5.
 - VIII. Claim 19, drawn to DNA encoding an LIPG polypeptide, classified in class 435, subclass 198.
 - IX. Claim 20, drawn to LIPG polypeptide, classified in class 435, subclass 198.

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- X. Claims 21 and 22, drawn to LIPG expression enhancer, classified in class 530, subclass 350.
- XI. Claims 23-27, 29, 30, 32-36, 38, 39 and 43, drawn to a method for raising HDL by lowering the level of LIPG, classified in class 514, subclass 44.
- XII. Claims 28, 40 and 42, drawn to a method for raising HDL by administering anti-LIPG antibody, classified in class 424, subclass 130.1.
- XIII. Claims 31 and 37, drawn to a method for raising HDL by administering a ribozyme which cleaves mRNA encoding LIPG, classified in class 514, subclass 44.
- XIV. Claim 41, drawn to a method for raising HDL by administering DNA encoding intracellular binding protein, classified in class 514, subclass 44.
- XV. Claim 44, drawn to a method for raising HDL by administering apolipoprotein AI, classified in class 514, subclass 2.
- XVI. Claims 45-48, drawn to a method for lowering VLDL by increasing LIPG activity, classified in class 424, subclass 94.1.
- XVII. Claims 45 and 49, drawn to a method for lowering VLDL by administering an LIPG activity enhancer, classified in class 514, subclass 2.
- XVIII. Claims 45 and 50, drawn to a method for lowering VLDL by administering an LIPG expression enhancer, classified in class 514, subclass 44.
- XIX. Claims 51 and 52, drawn to a method for lowering LDL by increasing LIPG enzymatic activity, classified in class 514, subclass 2.

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- XX. Claims 51, 53-56, drawn to a method for lowering LDL by administering an LIPG expression vector, classified in class 514, subclass 44.
 - XXI. Claim 57, drawn to a method for lowering LDL by administering an enhancer of enzymatic reactions, classified in class 514, subclass 2.
 - XXII. Claim 58, drawn to a method for lowering VLDL by administering an enhancer of enzymatic reactions, classified in class 514, subclass 2.
 - XXIII. Claims 59-62, drawn to a method comprising measuring LIPG polypeptide levels, classified in class 435, subclass 19.
 - XXIV. Claim 63, drawn to a method for determining LIPG-HDL-apoAI enzymatic reaction inhibitors, classified in class 435, subclass 4.
 - XXV. Claim 64, drawn to a method for determining LIPG-VLDL enzymatic reaction enhancers, classified in class 435, subclass 4.
 - XXVI. Claim 65, drawn to a method for determining LIPG-LDL enzymatic reaction enhancers, classified in class 435, subclass 4.
2. The inventions are distinct, each from the other because of the following reasons:
- Each of Groups I-X is directed to a separate and distinct invention. Group I is directed to LIPG antisense DNA, Group II is directed toward anti-LIPG antibody, Group III is directed toward DNA encoding anti-LIPG antibody, Group IV is directed toward intracellular binding protein, Group V is directed toward DNA encoding intracellular binding protein, Group VI is directed toward LIPG enzymatic activity inhibitor, Group VII is directed toward ribozyme LIPG.

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expression inhibitor, Group VIII is directed toward DNA encoding an LIPG polypeptide, Group IX is directed toward LIPG polypeptide and Group X is directed toward an LIPG expression enhancer.

The products of Groups I-X would be expected to have distinct morphological, functional, chemical and physical properties as indicated by their divergent classification, process of making and process of using. These products are capable of separate manufacture, use, or sale as claimed, and are patentably distinct.

3. Each of Groups XI-XXVI is directed to a separate and distinct invention. Group XI is directed to a method of raising HDL by lowering the level of LIPG, Group XII is directed to a method of raising HDL by administering anti-LIPG antibody, Group XIII is directed to a method of raising HDL by administering a ribozyme which cleaves mRNA encoding LIPG, Group XIV is directed to a method of raising HDL by administering DNA encoding intracellular binding protein, Group XV is directed to a method of raising HDL by administering apolipoprotein AI, Group XVI is directed to a method of lowering VLDL by increasing LIPG activity, Group XVII is directed to a method of lowering VLDL by administering an LIPG activity enhancer, Group XVIII is directed to a method of lowering VLDL by administering an LIPG expression enhancer, Group XIX is directed to a method of lowering LDL by increasing LIPG enzymatic activity, Group XX is directed to a method of lowering LDL by administering an LIPG expression vector, Group XXI is directed to a method of lowering LDL by administering an enhancer of enzymatic reactions, Group XXII is directed to a method of lowering VLDL by administering an enhancer of

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enzymatic reactions, Group XXIII is directed to a method comprising measuring LIPG polypeptide levels, Group XXIV is directed to a method of determining LIPG-HDL-apoAI enzymatic reaction inhibitors, Group XXV is directed to a method of determining LIPG-VLDL enzymatic reaction enhancers and Group XXVI is directed to a method of determining LIPG-LDL enzymatic reaction enhancers. These methods are distinct both physically and functionally, require different process steps, reagents and parameters and produce different products.

4. Inventions of Group I and Group XI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product can be used in a different process such as a probe or primer.

5. Inventions of Group II and Group XII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product can be used in a different process such as for detecting the presence of LIPG polypeptide.

6. Inventions of Group VII and Group XIV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the

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process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product can be used in a different process such as in an assay for LIPG DNA.

7. Inventions of Group IX and Group XVI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product can be used in a different process such as in the production of anti-LIPG antibodies.

8. Inventions of Group X and Group XVIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product can be used in a different process such as in the production of anti-LIPG expression enhancer antibodies.

9. Inventions of Group IX and Group XIX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that

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product (MPEP § 806.05(h)). In the instant case the product can be used in a different process such as in the production of anti-LIPG antibodies.

10. Inventions of Group VIII and Group XX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product can be used in a different process such as in the production of LIPG polypeptide.

11. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

12. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

13. Due to the number of groups in the restriction, a written restriction requirement is sent.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

14. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently

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named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Peter Tung, Ph.D. whose telephone number is (703) 308-9436. The examiner can normally be reached on Monday-Friday from 9:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy, Ph.D., can be reached on (703) 308-3804. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



PONNATHAPU ACHUTAMURTHY
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600